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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,094	06/19/2006	Selwayan Saini	P08828US00/BAS	8178
881 7590 06/24/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER HAQ, SHAFIQUL	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 06/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,094

Applicant(s)

SAINI ET AL.

Examiner

SHAFIQU HAQ

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- _____ Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- _____ Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of claims

1. Claim 1-9 are pending and are examined on merits.

Claim Objections

2. In claim 4, there is no period at the end of the claim (after the chemical formula).
This format does not conform to M.P.E.P 608.01 (m) since each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 1 recites "conjugating a hapten having a $\text{CH}_3\text{O}-\text{C}(\text{CH}_3)_2-\text{CH}_2-$ moiety to a carrier protein" in lines 1-3. The complete structure of the hapten is unclear because the term "hapten having a $\text{CH}_3\text{O}-\text{C}(\text{CH}_3)_2-\text{CH}_2-$ moiety" implies that the hapten have other moieties present in the compound. The linkage (position) of the carrier protein to the $\text{CH}_3\text{O}-\text{C}(\text{CH}_3)_2-\text{CH}_2-$ moiety is also unclear i.e. it is unclear the carrier protein is attached what atom of the $\text{CH}_3\text{O}-\text{C}(\text{CH}_3)_2-\text{CH}_2-$ moiety.

6. Claim 1 recites a step (i.e. step i) of conjugating a hapten having a $\text{CH}_3\text{O}-\text{C}(\text{CH}_3)_2-\text{CH}_2-$ moiety to a carrier protein to produce a conjugate. The conjugation step is unclear. It is unclear how the $\text{CH}_3\text{O}-\text{C}(\text{CH}_3)_2-\text{CH}_2-$ moiety is conjugated to the carrier protein. A clear step is required to show how the above group is coupled to the carrier protein (i.e. an activation step to incorporate a functional group/coupling group).
7. Claim 2 defines "X is a spacer" in line 3. The term "spacer" is not defined or described in the specification and thus it is unclear what compounds are encompassed by the term "spacer". Specification discloses MTBE-spacer-BSA polymer as 7-methoxy-3,7-dimethyloctanal-BSA (see example 1, page 19 of specification) which would provide 5 carbon alkylene chain as a spacer but specification does not disclose or describe any other compound that could be used as a spacer. Therefore, is it unclear what other compounds are encompassed by the term "spacer" in claim 2.
8. Claim 2 defines "B as a group capable of binding to a carrier protein" in line 3. The term "group capable of binding to a carrier protein" is not defined or described in the specification and thus it is unclear what groups are encompassed by the term "group capable of binding to a carrier protein". Specification discloses MTBE-spacer-BSA polymer as 7-methoxy-3,7-dimethyloctanal-BSA (see example 1, page 19 of specification) which contains an aldehyde group but specification does not disclose or suggest any other group usable together with the compound for binding to a carrier

protein. Therefore, is it unclear what other group applicants is intended to encompass by the term "group capable of binding to a carrier protein" in claim 2.

9. Claim 9 provides for the use of antibodies generated by the method according to claim 1 for immunoassay, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102/103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 8 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pourfarzaneh (US 6,416,671 B1)

Claim 8 is drawn to a monoclonal antibody capable of binding to methyl tert-butyl ether (MTBE).

Pourfarzaneh discloses MTBE mouse monoclonal antibody capable of binding to MTBE (see example 5 of column 18) and thus the antibody of Pourfarzaneh appears to be the same as or functionally equivalent to the antibodies of instant claim 8 because they have the same specificity i.e. capable of binding methyl tert-butyl ether (MTBE). The phrase "produced by the method of claim 1" has not given a patentable weight because the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. For product by process claim, see MPEP

2113. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The federal circuit affirmed, stating that "once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process." Once a product appearing to be substantially identical is found and a 35 USC 102/103 rejection made, the burden shifts to the applicant to show an unobvious difference. *In re Thorpe* 227 USPQ 964 (Fed. Cir. 1985); *In re Best* 195 USPQ 430 (CCPA 1977); *In re Fessman* 180 USPQ 324 (CCPA 1974); *In re Brown* 173 USPQ 685 (CCPA 1972).

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Examiner, Art Unit 1641